REMARKS

These Remarks are responsive to the issues presented in the Opinion of the Board of Appeals and Interferences dated May 19, 2009. Claims 1–43 have been cancelled and new claims 44–76 are presented. Specifically, as discussed below, the claims have been amended to define over the cited combination of Lawlis and Ward, and additional evidence has been submitted regarding the publicly available information regarding the chymosin gene from *Camelus dromedarius* and the existence of recombinant organisms expressing the same.

Support for the newly added claims is found throughout the original claims and specification. Claims 44 and 60 find support in at least original claims 1, 2, 4, 6, 8, 9, 29, and 30, and in page 6, lines 11–13 and Example 2 (particularly Tables 2.1 and 2.2 on pages 12–13) of the as-filed specification. Dependent claims 45–50 and 55–59 find support in originally filed claims 5, 6, 10, 11, 12, 18, 29, and 30. Support for the subject matter of claims 52–54 and 68–70 can be found in at least original claims 14–16 and Example 2 (particularly Tables 2.1 and 2.2 on pages 12–13) of the as-filed specification. Support for claims 51 and 67 can be found in at least page 9, lines 10–11 of the as-filed specification. No new matter is added by these amendments.

35 U.S.C. § 112, first paragraph, written description requirement

Claims 5, 6, 9–14, 16–18, 35, 36, 39, 42, and 43 were rejected under 35 U.S.C. § 112, first paragraph, for lack of adequate written description. The rejected claims have been canceled and new claims 44–76 are presented. The presently pending claims, as with the rejected claims, are directed to a process comprising, among other limitations, a "medium having a pH of 2.0 or higher is derived from the cultivation of an organism that is a bacterial species, a yeast species, or a species of filamentous fungi, wherein the organism comprises a gene for encoding chymosin that is derived from a bovine or *Camelidae* species."

At page 6, the Board Decision stated that "Appellant's Appeal Brief does not dispute the Examiner's finding that the prior art does not disclose the sequence of a chymosin gene from any species in the genus *Camelidae*." Applicants submit herewith evidence that the chymosin gene from *Camelus dromedarius* was publicly available at the time of the invention. Attached as Exhibit A is the EMBL Sequence Database entry for Camelus dromedarius mRNA for chymosin showing that the sequence was publicly available as of December 21, 2000. The effective filing date for the present application is February 9, 2001. Applicant respectfully requests reconsideration of the rejection for lack of written description based on the evidence that the chymosin gene from *Camelus dromedarius* was publicly available at the time of the invention.

Further, Applicant submits that not only was the chymosin gene known at the time of the invention, the commonly owned U.S. patent No. 7,270,989 makes reference to recombinant dgr246pyrG strain (Example 2) which expresses camel chymosin. *See* '989 Patent, col. 15, ll. 24–33. The '989 Patent states that chymosin producing recombinant strains #21 and #28 (see Example 3) were deposited on June 13, 2000 with the CBS repository under accession Nos. 108915 and 108916. The effective filing date for the present application is February 9, 2001. Applicant respectfully requests reconsideration of the rejection for lack of written description based on the evidence that the recombinant organisms expressing the chymosin gene from *Camelus dromedarius* had been deposited in the CBS repository under accession Nos. 108915 and 108916 at the time of the invention.

Applicant respectfully request that in view of the above publicly available information regarding the chymosin gene from *Camelus dromedarius* and the existence of recombinant organisms expressing the same, and the information regarding recombinant bovine chymosin described in the specification, the present claims fully comply with the written description

requirement of 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 112, first paragraph, enablement

Claims 5, 6, 9–14, 16–18, 35, 36, 39, 42, and 43 were rejected under 35 U.S.C. § 112, first paragraph, for lack of an enabling disclosure. The rejected claims have been canceled and new claims 44–76 are presented. The presently pending claims, as with the rejected claims, are directed to a process comprising, among other limitations, a "medium having a pH of 2.0 or higher is derived from the cultivation of an organism that is a bacterial species, a yeast species, or a species of filamentous fungi, wherein the organism comprises a gene for encoding chymosin that is derived from a bovine or *Camelidae* species."

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Applicant respectfully request that in view of the above publicly available information regarding the chymosin gene from *Camelus dromedarius* and the existence of recombinant organisms expressing the same, and the information regarding recombinant bovine chymosin described in the specification, the present claims fully comply with the enablement requirement of 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 103 Obviousness

Claims 5, 6, 9, 12–14, 16–18, 42 and 43 were rejected under 35 U.S.C. § 103(a) as obvious in view of Lawlis and Ward. The rejected claims have been canceled and new claims 44–76 are presented. Claims 44–59 as amended require a step of "lowering the pH of said medium having a pH of 2.0 or higher to between 1.0 and 1.8 by addition of lactic acid, acetic acid, propionic acid, or citric acid," while claims 60–76 as amended require "lowering the pH of said medium having a pH of 2.0 or higher to between 1.0 and 1.8 by addition of an inorganic acid."

Lawlis teaches a cell killing technique that involves adding an organic acid in a medium and lowering the pH of the medium to 2 pH units below the pKa of the organic acid. Lawlis teaches that a "preferred acid is acetic acid because it is effective with a wide range of cells and because it is one of the lowest cost acids available." Lawlis, col. 4, lines 49–51. Acetic acid has a pKa of approximately 4.7, and thus Lawlis teaches lowering the pH to 2.79 in the cell killing

step. Lawlis discloses that formic acid (pKa=3.75) can be used as a potential organic acid. Lawlis, col. 3, lines 51–64. In combination with Lawlis' teaching that the pH should be 2 pH units below the pKa of the organic acid, the use of formic acid would result in a pH of 1.75. The claims, however, cannot be met by the use of formic acid described in Lawlis as they now require an "inorganic acid" or "lactic acid, acetic acid, propionic acid, or citric acid" in combination with the claimed pH range. Applicant submits there would be no reason to lower the pH to meet the claimed range when practicing the cell killing method of Lawlis.

Ward fails to cure these deficiencies in Lawlis. Ward is discussed at page 2, lines 19–23, of the specification. Ward discloses improved production of bovine chymosin in recombinant *Aspergillus* by expression of a glucoamylase-chymosin fusion protein. *See* Ward, Title & Abstract. In particular, Ward teaches that the glucoamylase-chymosin fusion proteins can be secreted at higher efficiency compared to prochymosin. Ward, page 438, col. 1, last paragraph. Ward teaches that lowering the pH to 2 converts the fusion protein to chymosin and at least some pseudochymosin. Ward, page 439, col. 2, first paragraph. Ward teaches that "[p]resumably, this would eventually be further processed to mature chymosin under appropriate conditions." Ward, page 439, col. 2, first paragraph. Ward further teaches that "[p]seudochymosin is fairly stable at a pH below 3 or above 6 but is further processed to mature chymosin at pH 4.5." Ward, page 435, col. 1, first paragraph after the Abstract. Thus, Ward suggests raising the pH to 4.5 after activating the chymosin at a pH of 2.0 to convert any pseudochymosin to chymosin. Ward differs from the claimed invention in that there is no step of: "subjecting said medium to a pH in the range of 1.0 to 1.8 for a period of time sufficient to inactivate at least 50% of said glucoamylase activity while maintaining at least 75% of said chymosin activity."

As the combination of cited references Lawlis and Ward fails to teach or suggest the

currently claimed invention was a whole, Applicant respectfully requests that the rejection under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSIONS

Applicant submits that these amendments and new evidence overcomes all of the rejections as stated by the Board of Patent Appeals and Interferences in their decision dated May 19, 2009 and places the pending claims in condition for allowance. Should any issues remain to be discussed in this application, the undersigned may be reached by telephone. Please charge any fees due for consideration of this paper and reopening of prosecution to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,
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